Message

From: Buhl, Lynn M [lbuhl@kpmg.com]
Sent: 3/16/2018 10:33:29 PM
To: Schaefer, Kathy A [Kathy.Schaefer@mnk.com]
Subject: Audit Committee: Draft Presentation for Review
Attachments: Audit Committee GP Update v1.pptx

Kathy:

Attached is the first draft of the audit committee presentation. Please let me know if you would like more or less detail, and any additional content.

Thanks,

Lynn Buhl
Director, Advisory
KPMG LLP | 550 South Hope Street, Suite 1500 | Los Angeles, CA 90071
Office: 213.955.8601
lbuhl@kpmg.com

Audit Committee: Government Pricing Update

Kathy Schaefer

March, 2018

340B: Program Overview

- Government mandated maximum price that manufacturers can charge to specified entities (i.e., 340B participating entities).
- Why would the government dictate an otherwise commercial price? Government wants participating entities to be able to leverage the government's national purchasing power.
- Quantification of the maximum amount 340B entities can be charged is based on the Medicaid reimbursement calculation.
- Generally, sales to 340B entities are excluded from government pricing calculations (i.e., cannot set a best price).
- Participation:
  - Manufacturers with covered outpatient drugs participating in Medicaid have to participate in 340B program.
  - Entities (e.g., disproportional share hospitals, AIDS clinics, Tribal/Urban health centers) have to register for the program.

340B: MNK's Participation

- MNK ARD and SpecGX participate in the 340B program.
- MNK Hospital Products does not currently participate.
  - MNK has informed the program administer - Health Resources and Services Administration (HRSA) – of its decision not to participate and supporting rationale:
    - Ofirmev does not qualify as a covered outpatient drug.
    - MNK Hospital Products is a separate legal entity from MNK Inc. and MNK Hospital Products does not participate in the Medicaid program.
  - MNK Hospital Products may reconsider its position if HRSA's Civil Monetary Penalties Rule ("CMP Final Rule") becomes effective on 7/1/18 (note: it has already been delayed four times, and it is unclear whether it will go into effect).
  - Participation would have a significant negative financial impact (~ $24m).

Base Average Manufacture Price (Base AMP)

- The government is clearly concerned with the rate of pharmaceutical price increases.
- For Medicaid, manufacturers have to pay the amount above inflation (inflation penalty/additional rebate) in addition to the basic rebate.
- The additional rebate is calculated using Base AMP.
- Generally the Base AMP is:
  - Brands: AMP for the first full quarter of sales.
  - Generics: AMP for the fifth full quarter of sales.
- Changing a Base AMP can be a gray area, but has been allowed in certain circumstances (e.g., 2007 DRA Final Rule provided manufacturers with the option to recalculate the baseline AMP for a drug in accordance with the final rule).

Acthar Base AMP

- CMS approved Questcor's request to change Acthar's Base AMP in 2010 following the FDA's approval to use Acthar to treat infantile spasms, and the subsequent label update.
- CMS later retracted its approval and said Acthar had to revert to the Base AMP established in 1990.
- MNK has had numerous exchanges with CMS on this topic. Most recently, MNK sent an email to CMS on April 14, 2017. CMS has not responded.
- Using the 1990 Base AMP would result in a significant impact to the unit rebate amount (URA) used for Medicaid rebate payments, due to an increase to the inflation penalty portion of the rebate. The liability would be retroactive to 2010 through current, and would be in the hundreds of millions of dollars.

Industry Hot Topics – Transparency Reporting

- States, counties, and cities are taking it upon themselves to address rising drug costs.
- Many are introducing regulations, aimed at gaining greater transparency related to drug prices. Examples include:
  - CA: Requires reporting drug price increases that cause the WAC to increase by 16% or more over the previous two calendar years plus the current calendar year.
  - Chicago: Requires notification of WAC increases or launch of new products with a 12 month WAC exceeding a certain threshold.
- Challenges:
  - Resourcing to meet expanding list of reporting requirements.
  - Different data sets, reporting formats for each location.
- How will required reporting impact future price increases?